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A U.S. Biodefense Strategy Primer

D. Poulin

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Homeland Security

Biodefense Knowledge Center

A U.S. Biodefense Strategy Primer

The anthrax mailings that followed the attacks of September 11, 2001 highlighted the need for a comprehensive national strategy to prevent, prepare for, respond to, and mitigate the effects of biological attacks. The goal of U.S. biodefense strategy is to reduce the likelihood of a future biological event, improve overall U.S. public health security, and minimize the economic and social disruption of a biological incident. Presidential communications, federal legislation, and executive agency planning documents provide the foundation for this strategy.

Central to current U.S. biodefense strategy is the 2004 Homeland Security Presidential Directive (HSPD) 10, *Biodefense for the 21st Century*, which states that “the United States will use all means necessary to prevent, protect against, and mitigate biological weapons attacks perpetrated against our homeland and our global interests.” HSPD-10 also sets forth four pillars of U.S. biodefense:

- **Threat awareness** includes timely, accurate, and relevant intelligence, threat assessment, and the anticipation of future threats.
- **Prevention and protection** involve continuing and expanding efforts to limit access to agents, technologies, and knowledge to certain groups and countries as well as protecting critical infrastructure from the effects of biological attacks.
- **Surveillance and detection** provide early warning or recognition of biological attacks to permit a timely response and mitigation of consequences as well as attribution.
- **Response and recovery** include pre-attack planning and preparedness, capabilities to treat casualties, risk communications, physical control measures, medical countermeasures, and decontamination capabilities.

HSPD-10 calls for the involvement and coordination of many federal department and agencies in national biodefense preparedness and response:

- The Secretary of Homeland Security is designated as the principal federal official responsible for managing and coordinating federal operations to prepare for, respond to, and recover from domestic incidents involving biological weapons. The directive also charges the Secretary of Homeland Security with coordinating, as appropriate, with the heads of other federal departments and agencies, to effectively accomplish this mission.
- The Secretary of State is the principal federal official responsible for responding to terrorist incidents that take place outside of U.S. borders, including U. S. support for foreign consequence management.
- The Department of Health and Human Services (HHS) is the lead agency for medical and public health response to such mass casualty events.
- The U.S. Department of Agriculture (USDA) directs the protection of agriculture and certain



food products.

- The Department of Defense (DOD) is in charge of military force protection.

The roles and responsibilities of these and other relevant federal, state, and local agencies involved in the national biodefense strategy are outlined in the **National Response Framework** (see **sidebar** on page 7).

A high-level summary of select presidential directives, public laws, and key international treaties and regimes follows. Where available, links to the official documents are provided.

Select Presidential Directives:

- **National Security Decision Memorandum 35 (1969)** renounced the use of lethal or incapacitating methods of biological warfare and confined U.S. biological programs to research and development for defensive purposes. It further authorized the destruction of stockpiles of biological weapons. This effort was expanded in **National Security Decision Memorandum 44 (1970)**, which renounced the use of toxins either from bacteriological or biological processes, or from chemical synthesis, and ordered the destruction of all stockpiles of such toxins. These memorandums effectively ended the U.S. offensive biological weapons programs.

National Security Decision Memorandum 35,
<http://www.state.gov/r/pa/ho/frus/nixon/e2/83596.htm>

National Security Decision Memorandum 44,
<http://www.state.gov/r/pa/ho/frus/nixon/e2/83628.htm>

- **Homeland Security Presidential Directive 4, the National Strategy to Combat Weapons of Mass Destruction (2002)**, set forth a national strategy that consists of three pillars: counter proliferation, nonproliferation, and consequence management, to prevent, deter, and defend against terrorist use of weapons of mass destruction (WMD).
- **Homeland Security Presidential Directive 7, Critical Infrastructure Identification, Prioritization, and Protection (2003)**, established a national policy for federal departments and agencies to identify and prioritize critical infrastructure and key resources and to protect them from terrorist attacks.

Homeland Security Presidential Directive 7, *Critical Infrastructure Identification, Prioritization, and Protection*,
http://www.dhs.gov/xabout/laws/gc_1214597989952.shtm

- **Homeland Security Presidential Directive 9, Defense of United States Agriculture and Food (2004)**, established agriculture and food system policy to protect against terrorist attacks, disasters, and emergencies. The directive stipulated that this policy be carried out by establishing protection requirements, creating early warning capabilities, reducing vulnerabilities, and enhancing screening, response, and recovery efforts. It also directed the Secretary of Agriculture to develop a National Veterinary Stockpile containing vaccines, antivirals, and therapeutics against animal diseases, and to develop a National Plant Disease Recovery System for maintaining economically important crops.

Homeland Security Presidential Directive 9, *Defense of United States Agriculture and Food*,
http://www.dhs.gov/xabout/laws/gc_1217449547663.shtm

- **Homeland Security Presidential Directive 10, Biodefense for the 21st Century (2004)**, provided a roadmap for U.S. biodefense capabilities. This directive set forth four pillars of

national biodefense: (i) threat awareness, (ii) prevention and protection, (iii) surveillance and detection, and (iv) response and recovery. Additional areas of focus included assessments of the biological weapons threat, international cooperation to reduce access to biological agents, identification and protection of critical infrastructure, early detection and warning systems, care of casualties, development of medical countermeasures, and decontamination strategies and technologies.

Homeland Security Presidential Directive 10, *Biodefense for the 21st Century*,
http://www.dhs.gov/xabout/laws/gc_1217605824325.shtm

- **Homeland Security Presidential Directive 18, Medical Countermeasures against Weapons of Mass Destruction (2007)**, defined a two-tiered approach for medical countermeasures, which included (i) focused agent-specific medical countermeasure research, development, and procurement efforts and (ii) development of a flexible medical countermeasures capability for emerging and future CBRN threats. This directive stipulated that the Secretary of HHS shall lead efforts related to public health and domestic preparedness, while the Secretary of Defense shall lead efforts regarding threats to military personnel and that the two Secretaries shall ensure their efforts are coordinated. The directive also required the Secretary of DHS to develop an all-CBRN risk assessment using intelligence, law enforcement, scientific, medical, and public health information.

Homeland Security Presidential Directive 18, *Medical Countermeasures against Weapons of Mass Destruction*,
http://www.dhs.gov/xabout/laws/gc_1219175362551.shtm

- **Homeland Security Presidential Directive 21, Public Health and Medical Preparedness (2007)**, established a strategic approach for protecting the health of Americans against disasters, including terrorist attacks, disease pandemics, or other naturally occurring calamitous events. The focus and major objectives of this directive's strategy include biosurveillance, countermeasure stockpiling and distribution, mass casualty care, and community resilience. The directive also established a Public Health and Medical Preparedness Task Force to implement this strategy.

Homeland Security Presidential Directive 21, *Public Health and Medical Preparedness*,
http://www.dhs.gov/xabout/laws/gc_1219263961449.shtm

Select Public Laws:

- **U.S. Public Law 101-298, the Biological Weapons Anti-terrorism Act of 1989**, implemented the Biological and Toxin Weapons Convention in the United States, imposing federal criminal sanctions for acquiring, retaining, developing, producing, stockpiling, transferring, or possessing biological agents, toxins, or delivery systems for use as a weapon. Provisions in the law allow these activities for prophylactic, protective, and other peaceful purposes.
- **U.S. Public Law 102-182, Title III, the Chemical and Biological Weapons Control and Warfare Elimination Act of 1991**, declared U.S. policy to seek international cooperation to control the proliferation of chemical and biological weapons and strengthen controls on access to chemical precursors, agents, and equipment. This law also amended the Export Administration Act of 1979 to include a list of goods and technologies that could be used in acquiring such agents. Both this act and the Arms Export Control Act of 1976 were amended to allow for imposition of sanctions against foreign persons found to be assisting a country in the acquisition, use, or stockpiling of chemical or biological weapons.
- **U.S. Public Law 107-56, the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001**,

establishes new crimes, penalties, and procedural techniques for use against domestic and international terrorists. There are two main sections that pertain to biological weapons. First, “Section 817. Expansion of the biological weapons statute,” includes certain provisions put forth by **H.R. 3160, the Bioterrorism Prevention Act of 2001**, limits the possession of select agents to reasonable quantities for research purposes, and prevents the possession of select agents by restricted persons including illegal aliens and convicted criminals. Second, “Section 1013. Expressing the sense of the senate concerning the provision of funding for bioterrorism preparedness and response,” calls for an investment to improve bioterrorism preparedness, response, food safety, and surveillance capabilities.

Public Law 107–56, Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001,

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ056.107.pdf

H.R. 3160, Bioterrorism Prevention Act of 2001,

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_bills&docid=f:h3160eh.txt.pdf

- **U.S. Public Law 107–188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**, directed the Secretary of HHS to create a strategy for responding to acts of bioterrorism and other public health emergencies, including the development of medical countermeasures against biological agents and toxins. This act established an Assistant Secretary for Public Health Emergency Preparedness within HHS to oversee these activities. Additionally, the Secretary of HHS was directed to maintain a strategic national stockpile of drugs, vaccines, medical devices, and other supplies in the event of a public health emergency and to improve state, local, and hospital preparedness for such emergencies. The act called for enhanced control of certain biological agents and toxins related to human and animal health, which has become known as the Select Agent Program, overseen by HHS’s Centers for Disease Control and Prevention (CDC) and USDA’s Animal and Plant Health Inspection Service (APHIS).

Public Law 107–188, Public Health Security and Bioterrorism Preparedness and Response Act of 2002,

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ188.107.pdf

- **U.S. Public Law 107–296, the Homeland Security Act of 2002**, created the Department of Homeland Security (DHS) to prevent terrorist attacks, reduce U.S. vulnerability to terrorist attacks, and minimize damage and assist in recovery from terrorist attacks that occur in the United States. The act created and defined the roles of several DHS directorates: (i) Information Analysis and Infrastructure Protection, (ii) Science and Technology, (iii) Border and Transportation Security, and (iv) Emergency Preparedness and Response. The act required the Secretary of DHS to coordinate with the Secretary of HHS on activities related to countermeasures against CBRN threats. It also enabled the DHS secretary to establish or contract with federally funded research and development centers to provide independent analysis of homeland security issues. The act created the Homeland Security Advanced Research Projects Agency (HSARPA) to award grants to support security-related research and technology development, and it transferred oversight of the Department of Agriculture’s Plum Island Animal Disease Center (PIADC) to DHS.

Public Law 107–296, Homeland Security Act of 2002,

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ296.107.pdf

- **U.S. Public Law 108–276, the Project BioShield Act of 2004**, authorized HHS to fund expedited research, development, and acquisition of priority medical countermeasures to be used in emergencies following terrorist attacks perpetrated using CBRN agents. Countermeasures include drugs, biological products, or devices for treatment, agent identification, and/or disease prevention. The BioShield Special Reserve Fund was created with approximately \$5.6B to fund these activities for FY2004 through FY2013. According to this act, countermeasures can only be procured using this fund if several criteria are met, including the Secretary of DHS identifying an agent as a material threat to national security. This act also directs the Secretary of HHS to coordinate with the Secretary of DHS regarding maintenance and deployment of the Strategic National Stockpile.

U.S. Public Law 108–276, the Project BioShield Act of 2004,

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ276.108.pdf

- **U.S. Public Law 109-417, the Pandemic and All-Hazards Act (2006)**, granted HHS additional authority related to the development of medical countermeasures, including countermeasures against biological agents causing public health emergencies not caused by a terrorist attack. This act requires the Secretary of HHS to lead the federal public health and medical response to public health emergencies. Additionally, it established the office of Assistant Secretary for Preparedness and Response and the Biomedical Advanced Research and Development Authority (BARDA) within HHS to improve national medical preparedness and countermeasure development and procurement. It is also the enabling legislation for the National Biodefense Science Board, which was established to provide advice and guidance to the HHS Secretary on scientific, technical, and other matters of special interest to HHS regarding activities to prevent, prepare for, and respond to adverse health effects of public health emergencies resulting from chemical, biological, nuclear, and radiological events, whether naturally occurring, accidental, or deliberate.

U.S. Public Law 109-417, the Pandemic and All-Hazards Act,

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ417.109.pdf

- **U.S. Public Law 110-53, Implementing Recommendations of the 9/11 Commission Act of 2007**, enacted wide-ranging legislation with many components affecting U.S. biodefense efforts, including (i) replacing the DHS Directorate of Information Analysis and Infrastructure Protection with the Office of Intelligence and Analysis and a separate Office of Infrastructure Protection as one step to improve information sharing and (ii) forming a National Biosurveillance Integration Center (NBIC) within DHS to provide early detection and warning of biological threats. The directive also expanded U.S. efforts to prevent the proliferation of WMD, by establishing a coordinator for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism and a Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism.

U.S. Public Law 110-53, Implementing Recommendations of the 9/11 Commission Act of 2007,

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ053.110.pdf

Key International Treaties and Regimes:

- **Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (1974)**, also known as the Biological Weapons Convention (BWC), is an international treaty intended to eliminate the use of biological agents and toxins as weapons. The BWC was ratified by the U.S. Senate in 1974

and entered into force on March 26, 1975. As of 2008 it had been signed by more than 150 nations.

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction,
<http://www.state.gov/www/global/arms/treaties/bwc1.html>

- The **Australia Group (1985)** is an informal forum of over 40 countries which, through the harmonization of export controls, seeks to ensure that exports do not contribute to the development of chemical or biological weapons. The principal objective of the Australia Group is to use licensing measures to ensure that exports of certain chemicals, biological agents, and dual-use chemical and biological manufacturing facilities and equipment do not contribute to the spread of chemical and biological weapons. Coordination of national export control measures assists Australia Group participants to fulfill their obligations under the Chemical Weapons Convention and the Biological and Toxin Weapons Convention to the fullest extent possible.

Australia Group (1985),
<http://www.australiagroup.net/en/index.html>

- **United Nations Security Council Resolution 1540 (2004)** is directed against the proliferation of weapons of mass destruction, their means of delivery, and related equipment and materials. All United Nations (UN) member states have three primary obligations under the resolution relating to chemical, nuclear, and biological weapons, related items and their delivery systems: (i) to refrain from providing support to non-state actors seeking such items; (ii) to prohibit non-state actors from engaging in specified activities relating to WMD, including the acquisition and use, the attempted acquisition and use, and the financing of the acquisition and use of such items; and (iii) to take and enforce effective measures to establish domestic controls to prevent the proliferation of nuclear, chemical, or biological weapons and their means of delivery, including by establishing appropriate controls over related materials. The resolution also places requirements on UN Member States to take specific measures to criminalize activities which can contribute to or support proliferation activities.

United Nations Security Council Resolution 1540,
<http://www.state.gov/t/isn/73519.htm>

National Response Framework

The **National Response Framework (2008)** provides guidance for implementing the nationwide response and operational coordination for all types of domestic incidents. The Biological Incident Annex contains information specific to the response to a biological attack or outbreak and outlines the actions, roles, and responsibilities of federal, state, and local agencies. The annex includes provisions for threat assessment notification procedures, laboratory testing, joint investigative and response procedures, and recovery activities. Other relevant annexes include Emergency Support Function (ESF) #8 – Public Health and Medical Services Annex, ESF #10 – Oil and Hazardous Materials Response Annex, ESF #11 – Agriculture and Natural Resources Annex, ESF #15 – External Affairs Annex, the Terrorism Incident Law Enforcement and Investigation Annex, and the International Coordination Support Annex. Links to the official documents are provided below.

National Response Framework,
<http://www.fema.gov/pdf/emergency/nrf/nrf-core.pdf>

Biological Incident Annex,
http://www.fema.gov/pdf/emergency/nrf/nrf_BiologicalIncidentAnnex.pdf

ESF #8 – Public Health and Medical Services Annex,
<http://www.fema.gov/pdf/emergency/nrf/nrf-esf-08.pdf>

ESF #10 – Oil and Hazardous Materials Response Annex,
<http://www.fema.gov/pdf/emergency/nrf/nrf-esf-10.pdf>

ESF #11 – Agriculture and Natural Resources Annex,
<http://www.fema.gov/pdf/emergency/nrf/nrf-esf-11.pdf>

ESF #15 – External Affairs Annex,
<http://www.fema.gov/pdf/emergency/nrf/nrf-esf-15.pdf>

Terrorism Incident Law Enforcement and Investigation Annex,
http://www.learningservices.us/pdf/emergency/nrf/nrf_terrorismincidentlawenforcementannex.pdf

International Coordination Support Annex,
<http://www.fema.gov/pdf/emergency/nrf/nrf-support-internatl.pdf>

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